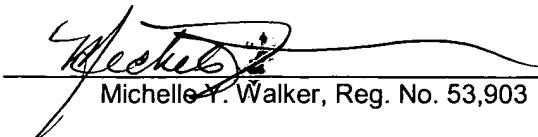




CERTIFICATE OF MAILING

I hereby certify that this paper is being deposited with the U.S. Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313, on December 31, 2003

  
Michelle T. Walker, Reg. No. 53,903

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of:

DREON et al.

Attorney Docket No.: 0125-UTL

Serial No 10/612,118

Art Group : unassigned

Filed: 7/2/2003

Examiner; unassigned

Title: Compositions and Methods For Reduction of Inflammatory Symptoms and/or Biomarkers in Female Subjects

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

**INFORMATION DISCLOSURE STATEMENT**

Transmitted herewith for filing in the above identified Application, under 37 C.F.R. 1.97, are an information Disclosure Statement and completed PTO Form 1449, along with referenced documents B1-B9, and C1-C16. Also included is a Return Receipt Postcard.

Identification of Time of filing the Information Disclosure Statement and any Required Certification or Petition

The Information Disclosure Statement is being submitted: (a) within three (3) months of the filing date, or (b) before the mailing date of a first Office action on the merits. **Therefore no fee is due or certification is required under 37 C.F.R. 1.97 (b).**

The Information Disclosure Statement is being submitted more than three (3) months after the filing date and after the mailing date of the first Office action on the merits, but before a final action under § 1.313 or a notice of allowance under § 1.311, whichever occurs first. The undersigned hereby certifies under 37 C.F.R. 1.97(e)(1) that each item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office on a counterpart foreign application not more than (3) months prior to the filing of the Information disclosure Statement. **Therefore, no fee is due under 37 C.F.R. 1.97 (c).**

- The Information Disclosure Statement is being submitted more than three (3) months after the filing date and after the mailing date of the first Office action on the merits, but before a final action under § 1.313 or a notice of allowance under § 1.311, whichever occurs first. The undersigned hereby certifies under 37 C.F.R. 1.97 (e) (2) that no item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a foreign counterpart application, or to undersigned's knowledge after making reasonable inquiry, was known to any person designated in §1.56 (c) more than (3) three months prior to the filing of the Information Disclosure Statement. **Therefore, no fee is due under 37 CFR 1.97 (c).**
- The Information Disclosure Statement is being submitted after the mailing date of a final action under § 1.313 or a notice of allowance under § 1.311, whichever occurs first, but before, or simultaneously with, payment of the issue fee.
  - The undersigned hereby certifies under 37 C.F.R. 1.97(e)(1) that each item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office on a counterpart foreign application not more than three (3) months prior to the filing of the Information Disclosure Statement.
  - Applicant(s)' attorney hereby certifies under 37 C.F.R. 1.97(e)(2) that no item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a foreign counterpart application, or, to the undersigned Attorney's knowledge after making reasonable inquiry, was known to any person designated in §1.56 (c) more than (3) three months prior to the filing of the Information Disclosure Statement.

## **2. Fee calculation and Deposit Account Authorization**

- The Information Disclosure Statement is being submitted more than three (3) months after the filing date and after the mailing date of the first Office action on the merits, but before a final action under § 1.313 or a notice of allowance under § 1.311, whichever occurs first, without certification under 37 C.F.R. 1.97(e). Therefore, *only if this entry is checked in the left margin, the \$ 180.00* fee set forth in §1.17 (p) is authorized below.

Applicant(s) hereby petition requesting consideration of the Information Disclosure Statement. *Therefore only if this entry is checked in the left margin, the \$180.00* petition fee set forth in § 117(i) is authorized below

- Please charge \$ \_\_\_\_\_ to Deposit Account No. **50-2247**
- The Commissioner is hereby authorized to charge any additional fees or credit any overpayment to Deposit Account No. 50-2247. This is not however, an authorization to pay the issue fee.

The Examiner is respectfully requested to consider these documents and to make them of record in the subject application.

Respectfully submitted,



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Date: December 31, 2003



**Form PTO-1449 (modified)**  
**Information Disclosure Statement by**  
**Applicant**

**Sheet 1 of 1**

**ATTY. DOCKET NO.**  
**0125-UTL**  
**SERIAL NO.**  
**10/612,118**

**APPLICANT**  
**DREON et al.**

**FILING DATE**  
**7/2/2003**  
**GROUP**

**U.S. Patent Documents**

Exam. Init.	Cite No.	Document Number	Name	Date MM-DD-YYYY	Addl. Ref.
	A1	4,758,592	Horrobin et al.	07-19-1988	
	A2	4,874,603	Fratzer	10-17-1989	
	A3	4,977,187	Horrobin	12-11-1990	
	A4	5,120,760	Horrobin	06-09-1992	
	A5	5,296,370q	Martin et al.	03-22-1994	
	A6	5,591,772	Lane et al.	01-07-1997	
	A7	5,750,516	Nakamura et al.	05-12-1998	
	A8	5,776,978	Bruzze	07-07-1998	
	A9	6,054,128	Wakat	04-25-2000	
	A10	6,103,755	Bumann	08-15-2000	
	A11	6,187,811	Lane	02-13-2001	
	A12	6,346,544	Hensley et al.	02-12-2002	
	A13	6,361,806	Allen	03-26-2002	
	A14	6,391,309	Emple et al.	05-21-2002	
	A15	6,479,545	Levinson, et al.	11-12-2002	
	A16	6,617,349	Green et al.	09-09-2003	
	A17	6,645,514	Schneider et al.	11-11-2003	
	A18	2002/0015742	Jackson et al.	02-07-2002	
	A19	2002/0068100	Kapoor et al.	06-06-2002	
	A20	2002/0143049	Miller et al.	10-03-2002	
	A21	2002/0173510	Levinson et al.	11-21-2002	
	A22	2003/0013693	Guivarc'h et al.	01-16-2003	
	A23	2003/0050341	Bydlon et al.	03-13-2003	

**Foreign Patent Documents**

Exam. Init.	Cite No.	Office	Document Number	Name	Date MM-DD-YYYY	Addl. Ref.	T
	B1		EP 0454102	Horrobin	10-31-1991		
	B2		EP 0573465	Martin	04-02-1997		
	B3		EP 0637957	Askanazi et al.	07-23-1997		
	B4		EP 0699437	Bruzze	03-06-1996		
	B5		EP 1260509	Brin et al.	11-27-2002		
	B6		EP 1275399	Kiliaan et al.	01-15-2003		
	B7		WO9929316	Mishra, et al.	06-17-1999		
	B8		WO02090977	Leeuwenburgh	11-14-2002		
	B9		WO03063793	Chilton et al.	08-07-2003		

**Other Documents**

Exam. Init.	Cite No.	(Including Author, Title, Date, Pertinent Pages, Etc.)	T
	C1	ABRAHAM, G.E. "Nutritional factors in the etiology of the premenstrual tension syndromes." J. Reprod. Med., July 1983, Vol. 28, No. 7, pages 446-464.	
	C2	CONNELL, E.B. et al. "C-reactive protein in pregnancy and contraception". Am. J. Obstet. Gynecol. July 1971, Vol. 110, No. 5, pages 633-639.	
	C3	DRUGSTORE.COM "Natrol DHA Neuromins, 100mg softgels" October 30, 2002. <a href="http://www.drugstore.com">www.drugstore.com</a>	



Serial No. 10/612,118  
IDS Submitted 12/31/03

	C4	DRUGSTORE.COM "Zone Perfect Omega 3 1000mg Capsules" October 30, 2002. <a href="http://www.drugstore.com">www.drugstore.com</a>	
	C5	FARMILA Dietary Supplements. "Fish Factor" November 8, 2002. <a href="http://www.farmila.it/otc/home_en.htm">http://www.farmila.it/otc/home_en.htm</a>	
	C6	JIANG, Q. et al. "Gamma-Tocopherol and its major metabolite, in contrast to alpha-tocopherol, inhibit cyclooxygenase activity in macrophages and epithelial cells". Proc. Natl. Acad. Sci. USA. October 10, 2000, Vol 97: No. 21, pages 11494-11499.	
	C7	LONDON, R.S. et al. "Efficacy of Alpha-tocopherol in the treatment of the premenstrual syndrome". J. Reprod. Med., June 1987, Vol. 32, No. 6, pages 400-404.	
	C8	LONDON, R.S. et al. "The effect of alpha-tocopherol on premenstrual symptomatology: a double-blind study." J. Am. Coll. Nutr. 1983, Vol. 2, pages 115-122.	
	C9	LONDON, R.S. et al. "The effect of alpha-tocopherol on premenstrual symptomatology: a double-blind study. II. Endocrine Correlates". J. Am. Coll. Nutr. 1984, Vol. 3, pages 351-356.	
	C10	RIDKER, P.M. et al. "C-reactive protein and other markers of inflammation in the prediction of cardiovascular disease in women." N. Engl. J. Med., March 2003, Vol 342, No. 12, pages 836-843	
	C11	SEELIG, M.S. "Interrelationship of magnesium and estrogen in cardiovascular and bone disorders, eclampsia, migraine and premenstrual syndrome". J. Am. Coll. Nutr. 1993, Vol. 12, No. 4, pages 442-458.	
	C12	TIDOW-KEBRITCHI, S. et al. "Effects of Diets Containing Fish Oil and Vitamin E on Rheumatoid Arthritis" Nutrition Reviews, October 2001, Vol 59, No. 10, pages 335-341.	
	C13	TORASSA, U. "Protein may help predict risk of heart attacks" San Francisco Chronicle, November 14, 2002. page A16 Col. 1	
	C14	Van Langendonckt, A. et al. "Oxidative stress and peritoneal endometriosis.". Fertility & Sterility, May 2002, Vol. 77, No. 5, pages 861-870.	
	C15	Vandenbroucke, J.P. et al. "Oral contraceptives and the risk of venous thrombosis". N. Engl. J. Med., May 2001, Vol. 344, No. 20, pages 1527-1535.	
	C16	TORASSA, U. "Protein may help predict risk of heart attacks" San Francisco Chronicle, November 14, 2002. page A16 Col. 1	
Examiner Signature		Date Considered	